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Section 5 - 510(k) Summary

1. **Applicant Contact:**

Lois Smart
Director, Quality Assurance and Regulatory Affairs
Quill Medical, Inc.
2505 Meridian Drive, Suite 150
Research Triangle Park, NC 27713
Phone: 919-806-1961
Fax: 919-806-1953
Email: lsmart@quillmedical.com

Date Prepared: August 29, 2005

2. **Name of Device:** Quill® Nonabsorbable Polypropylene Barbed Suture
Common Name: Nonabsorbable Polypropylene Surgical Suture
Classification Name: Nonabsorbable Polypropylene Surgical Suture
Regulation 21 CFR 878.5010, Product Code GAW

3. **Identification of device(s) to which the submitted claims equivalence:**

The Quill® Nonabsorbable Polypropylene Barbed Suture is substantially equivalent to the following predicate devices:

- For Material / Technological Characteristics:
  - Contour Midface Opposing Unidirectional Threads™ by Surgical Specialties Corp., 510k K050548
- For Indication for Use based on Technological Characteristics:
  - Quill® Synthetic Absorbable Barbed Suture by Quill Medical, Inc., 510k K051609

4. **Device Description:**

The Quill® Nonabsorbable Polypropylene Barbed Suture is a monofilament, flexible thread prepared from long chain polyolefin polymer. It is available sterile, dyed blue [Phthalocyaninato(2-)] copper (and also undyed) in various suture diameters, lengths and needle configurations. Each suture has bi-directional barbs along the long axis of the suture monofilament.

The Quill® Nonabsorbable Polypropylene Barbed Sutures approximate tissues by using the opposing barbs on the suture surface to imbed in the tissues after the surgeon precisely places the suture within the tissues. Each Quill® Nonabsorbable Polypropylene Barbed Suture pass provides the security of an interrupted suture strand without the added bulk of a knot. As with interrupted sutures, if the Quill® Nonabsorbable Polypropylene Barbed Suture breaks, the remaining suture passes will hold the wound edges in approximation.

Section E - 510(k) Summary (continued)

5. Intended Use of the Device:

Quill® Nonabsorbable Polypropylene Barbed Sutures are indicated for use in soft tissue approximation excluding closure of the epidermis.

6. Technological characteristics of the device in comparison to those of the predicate device(s)

Indication for Use Comparison:

The Quill® Nonabsorbable Polypropylene Barbed Suture is equivalent in its intended use of soft tissue approximation to the Quill® Synthetic Absorbable Barbed Suture.

Material and Technology Comparison:

The Quill® Nonabsorbable Polypropylene Barbed Suture is equivalent to the predicate device as shown in the table below:

	Quill® Nonabsorbable Polypropylene Barbed Suture, 510(k) TBD	Contour Midface Opposing Unidirectional Threads™, 510(k) K050548
Product Code	GAW	GAW
Technique of Deployment	Attached needles.	Attached needles.
Technological Characteristic	Bi-directional barbs along the long axis of the suture monofilament.	Bi-directional barbs along the long axis of the suture monofilament.
Material	Polypropylene (cleared per K904906)	Polypropylene (cleared per K904906)
Sterilization	EO	EO
Packaging	Identical (device wound onto cardboard inner support card and packaged in a Tyvek pouch)	Identical (device wound onto cardboard inner support card and packaged in a Tyvek pouch)

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Section E - 510(k) Summary (continued)

7. Safety and Performance:

The difference between the Quill® Nonabsorbable Polypropylene Barbed Suture and the above mentioned predicate devices do not raise any questions regarding the safety and effectiveness of the barbed suture. The Quill® Synthetic Absorbable Barbed Suture employs the same technological characteristics to support the intended use of soft tissue approximation of the nonabsorbable fiber (polypropylene) used in the Contour Midface Opposing Unidirectional Threads™. In addition, polypropylene is commonly used in medical applications and has proven to be biocompatible. The device, as designed, is as safe and effective as its predicate devices.

8. Conclusion

Based on the design, material, function and intended use discussed herein, Quill Medical believes the Quill® Nonabsorbable Polypropylene Barbed Suture is substantially equivalent to predicate devices currently marketed under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 2005

Ms. Lois V. Smart
Director, Quality Assurance and Regulatory Affairs
Quill Medical, Inc.
2505 Meridian Drive, Suite 150
Research Triangle Park, North Carolina 27713

Re: K052373
Trade/Device Name: Quill® Nonabsorbable Polypropylene Barbed Suture
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable polypropylene surgical suture
Regulatory Class: II
Product Code: GAW
Dated: August 29, 2005
Received: August 30, 2005

Dear Ms. Smart:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Barbara Buchner
for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K052373

Section 4 - Indications for Use Statement

510k number if known: _____

Device Name: Quill® Nonabsorbable Polypropylene Barbed Suture

Indications for Use:

Quill® Nonabsorbable Polypropylene Barbed Sutures are indicated for soft tissue approximation excluding closure of the epidermis.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052373